

## HEALTH PHYSICS SOCIETY

## RELEASE OF PATIENTS TREATED WITH THERAPEUTIC QUANTITIES OF RADIOPHARMACEUTICALS AND SEALED SOURCES

## POSITION STATEMENT OF THE HEALTH PHYSICS SOCIETY\*

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The Health Physics Society (HPS) has adopted a position that a dose-based criterion is appropriate to govern the release of patients who were treated with therapeutic quantities of radiopharmaceuticals or who received permanent implants of sealed radioactive sources for therapeutic purposes. The HPS considers the U.S. Nuclear Regulatory Commission (NRC) patient release dose criteria in 10 CFR 35.75 to provide ample public health safety measures.

The NRC patient release dose criteria (U.S. NRC 2001) allow patients to be released if the effective dose to any other individual is not likely to exceed 5 mSv per patient and require that the patient be given instructions, including written instructions, on actions recommended to maintain doses to other individuals as low as reasonably achievable (ALARA) if the total effective dose equivalent to any other individual is likely to exceed 1 mSv per patient. According to the HPS position statement "Radiation Risk in Perspective," these dose criteria are well below the lowest dose that justifies quantitative estimation of health risks (HPS 2010). Application of the dose criteria for release of patients should properly balance public-safety issues with the patient's access to treatment with therapeutic quantities of radiopharmaceuticals and sealed sources.

In response to comments on the 1997 10 CFR 35.75 rulemaking, the NRC stated the patient release dose criterion of 5 mSv applies to each patient release based on NRC staff's review that multiple administrations in the same year to the same patient were not expected to exceed 5 mSv to any other individual (U.S. NRC 1997a). Algorithms recommended in NRC guidance (U.S. NRC 1997b, 2008) for calculating projected dose from a released patient to other individuals are conservative in overestimating those doses (Siegel et al. 2007). Studies measuring dose to family members from released iodine-131 therapy patients have demonstrated that actual doses received are small and well below the patient release dose criteria (Grigsby et al. 2000; Pant et al. 2006; Rutar et al. 2001). The NRC Advisory Committee on the Medical Uses of Isotopes (ACMUI) used the extremely conservative NRC algorithms to evaluate various exposure scenarios from an iodine-131 patient released to a hotel and concluded that the dose to any other individual exposed to the iodine-131 therapy patient is not likely to exceed 1 mSv (U.S. NRC 2010). The HPS considers the NRC patient release dose criteria to be consistent with the HPS position statement "Ionizing-Radiation Standards for the General Public," which calls

for a general public limit of 1 mSv or, in special (infrequent) circumstances, a limit of 5 mSv in any one year (HPS 2009). The HPS discourages establishment of an annual dose limit for patient release criterion due to the potential for unnecessarily limiting a patient's access to treatment with therapeutic quantities of radiopharmaceuticals and sealed sources.

The Health Physics Society maintains that release of patients in accordance with 10 CFR 35.75 poses no discernible risk to the public, thus providing ample public health safety measures, and provides significant benefits to patients, their families, and society.

## References

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<sup>\*</sup>The Health Physics Society is a nonprofit scientific professional organization whose mission is excellence in the science and practice of radiation safety. Since its formation in 1956, the Society has represented the largest radiation safety society in the world, with a membership that includes scientists, safety professionals, physicists, engineers, attorneys, and other professionals from academia, industry, medical institutions, state and federal government, the national laboratories, the military, and other organizations. Society activities include encouraging research in radiation science, developing standards, and disseminating radiation safety information. Society members are involved in understanding, evaluating, and controlling the potential risks from radiation relative to the benefits. Official position statements are prepared and adopted in accordance with standard policies and procedures of the Society. The Society may be contacted at 1313 Dolley Madison Blvd., Suite 402, McLean, VA 22101; phone: 703-790-1745; fax: 703-790-2672; email: <u>HPS@BurkInc.com</u>.